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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,631	08/18/2003	Janet A. Tamada	ANMS-128US	4458

23122 7590 03/01/2006

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EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,631	TAMADA ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *22-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election without traverse of Group I, claims 1-21, in the reply filed on 1/6/06 is acknowledged. The IDS received 10/17/03 has been considered. Please inform the examiner of any related applications, pending, allowed or abandoned.

A reading of the specification reveals the point of novelty of the hydrogel resides in a high concentration of the phosphate buffer.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Burson, Burson and Abraham.

Each of the references teach sufficient phosphate buffer to maintain the desired pH range of 6-8. The present claims include no functional limitations regarding the concentration of the phosphate other than the buffer as a whole has a concentration range of 125-500 mM in the final composition.

Burson (6,615,078) entitled "Methods and Devices for Removing Interfering Species" teaches in column 12 lines 42-56, a hydrogel containing phosphate buffer at a pH of 6-8. In column 17 lines 26-29, the gel contains sodium phosphate monobasic 2.07 wt%, sodium phosphate dibasic 0.20 wt%. Other similar amounts are shown in column 17. See the claims.

Burson (US 2005/0170448) entitled "Methods of Manufacturing Glucose Measuring Assemblies with Hydrogels" teaches on page 9 paragraph 96, gel containing 0.22 wt% sodium phosphate monobasic, 2.25 wt% sodium phosphate dibasic. Another formulation contains 0.32 wt% sodium phosphate monobasic, 2.07 wt% sodium phosphate dibasic. A third formulation contains 0.26 wt% sodium phosphate monobasic, 2.17 wt% sodium phosphate dibasic

Abraham (US 2004/0062759 A1) entitled "Hydrogel Formulations for Use in Electroosmotic Extraction and Detection of Glucose" teaches on page 10 Table 2 a hydrogel containing 0.5 wt% phosphate buffer. On page 11 Example 6 the gel contains 0.26 g sodium dibasic phosphate and 2.17 g of monobasic phosphate at pH 7.4.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to provide a hydrogel composition with a phosphate buffer 125-500 mM as presently claimed in view of each of the above references because each of the references teach a hydrogel composition with the same components as claimed and a phosphate buffer of some sort at some concentration with different units than those presently claimed. One cannot positively distinguish the compositions of the references from that claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As claimed in claim 1, "a phosphate buffer present at a concentration of between about 125 mM and about 500 mM" is unclear because one would not know what exactly is included in the buffer composition and so could not then determine the concentration of the buffer. In claim 1 line 3, "a hydrophilic compound capable of forming a gel" does not positively state what the compound does. "Which forms a gel" is suggested. In claim 9 "e-beam" should be spelled out in the first occurrence in the claims.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kim (6,816,742, 6,587,705) teach a biosensor.

Burson (6,902,905, US 2003/0199745 A1)) teach glucose measuring with a hydrogel.

Abraham (WO 97/02811) teaches a hydrogel with 0.5% phosphate buffer.

Ackerman (ACS Symposium) teaches glucose monitoring with a hydrogel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ralph Gitomer
Primary Examiner
Art Unit 1655

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Primary Examiner
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